

REMARKS

The Official Action of March 19, 2009 objected to claims 2, 19, and 28, and 31-35 for certain informalities noted on page 2 of the Action. Claims 19, 24, 25, and 35 were rejected under 35 U.S.C. 102 as being anticipated by the Pisharodi '926 patent. Claims 19 and 24-27 were rejected under §102(b) as being anticipated by the Perren, *et al.* patent ("Perren"). Claims 2 and 28-34 were rejected under 35 U.S.C. 103 as being obvious over the combination of the Pisharodi '926 patent in view of either the Steffee '514 or Pisharodi '762 patents and claims 20-21 were rejected under that same section of the Statute as being obvious over the combination of those same three patents and Muhanna. Claims 22-23 were rejected under §103 over the combination of those same four patents and the Haldiman '576 patent. None of the §102 rejection of claims 2, 28, 29, and 31-35 over the Sertich patent, the §103 rejection of claims 19-21, 24, and 26 over the Ralph and Muhanna patents, the rejection of claims 22-23 over the combination of the Ralph, Muhanna, and Haldimann patents, or the §103 rejection of claim 30 over the combination of the Sertich and Pishardi '926 patents, all as set out in the Official Action of November 19, 2007, were renewed in the March 19, 2009 Official Action. Nevertheless, the objections/rejections set out in the March 19, 2009 Action are traversed, and in accordance with the requirements of 37 C.F.R. 1.111(b), the basis for traversing these rejections is set out below.

Applicant appreciates the suggested amendment for remedying the objection to claim 2 and claim 2 was amended to adopt the suggested language. Reconsideration and withdrawal of the objection is therefore respectfully requested.

Applicant has not amended claims 19, 28, or 32-35 in response to the objection to the word "resisting" recited in those claims. As explained in the Response to Official Action of November 19, 2008 (please note the typographical error in the title of that filing, which should have referred to a November 19, 2007 Official Action), Applicant defined this method step without regard to structure in contemplation of different ways for resisting rotation of the implant. Applicant respectfully traverses the allegation on page 2 of the March 19, 2009 Action that "the step of 'resisting' is . . . not a manipulative step but rather, a feature provided by the implant structure" insofar as that allegation has the effect of limiting the scope of claims 19, 28, and/or 32-35. Claims 19, 28, and 32-35 are all method claims and are not limited to specific structure (and one way that rotation can be resisted in accordance with the claimed method was suggested on page 6 of Applicant's Response to Official Action of November 19, 2008, *sic* 2007). If, for instance, claim 19 was an apparatus claim, the function recited in that claim might be inherent in the structure of the invention, but the invention was deliberately defined as a method in claim 19 (and in claims 28 and 32-35), and in the absence of prior art that requires

Applicant to amend claim 19 to patentably define over any such art, it is entirely appropriate for Applicant to define the invention as a method including the step of resisting rotation of the implant. Reconsideration and withdrawal of this objection to claims 19, 28, and 32-35 is respectfully requested.

The same analysis applies to the words “maintaining,” “resisting,” and “biasing” in claims 31 and 33-35, to which the Action also objects. Further, claim 31 uses the word “biasing” because it depends on claim 2 which recites the step of “biasing” (and the Action does not object to the use of that term in claim 2) such that claim 2 provides antecedent basis for “biasing” in claim 31. Again, it is noted that claims 31 and 33-35 are **method** claims and that a term such as the word “maintaining” in claim 31 is not intended to limit the claim to any particular structure for maintaining alignment while biasing an insert away from an implant. Because claim 33, which recites “limiting the movement of the insert,” is a method claim and “limiting” is one of the steps of the claimed method, it is entirely appropriate to recite the term “limiting” in that claim. Likewise, claims 34-35 recite resisting movement of the implant out of the intervertebral space. There are many ways to resist such movement, and this recitation is intended to cover the many ways to resist such movement when used in combination with the other steps of this method without regard to specific structure. Reconsideration and withdrawal of the objections to all of claims 19, 28, and 32-35 is respectfully requested.

The §102 rejection of claim 19 over the Pisharodi ‘926 patent is premised on the allegation that the bands 14 shown in Fig. 4 of that reference constitute the claimed insert. However, the claim recites the step of inserting an elongate implant “having an insert movably mounted thereto” into a disk space, “restraining the movable insert against movement relative to the implant,” and releasing the movable insert “to bias the movable insert into engagement” with an adjacent vertebra. Although the band 14 disclosed in the Pisharodi ‘926 patent is movable relative to the insert, band 14 is itself a restraining device, not an insert as defined in the claims of the captioned application. The fact that it is not an insert is illustrated by the complete lack of any disclosure in the Pisharodi ‘926 patent of biasing the band 14 into engagement with an adjacent vertebra. Instead, that reference describes (at col. 3, lines 44 *et seq.*) breaking the bands 14 (by pulling strings 16) so that the disk prosthesis 2 can expand in the disk space. Of course a disk prosthesis such as is described in the Pisharodi ‘926 patent is not an implant such as the implant described and claimed in the captioned in the first place, but without regard to that distinction, expansion of an implant in a disk space as described in the Pisharodi ‘926 patent is not the same as biasing a portion of an implant that is movably mounted to the implant into engagement with an adjacent vertebra as recited in claim 19. Further, if it is being alleged that

expansion of prosthesis 2 of the ‘926 patent is the same as biasing a portion of an implant into engagement with an adjacent vertebra as recited in claim 19, where does the Pisharodi ‘926 patent describe biasing the bands 14 into engagement with an adjacent vertebra? The bands 14 described in Pisharodi ‘926 are not biased at all, nor is there any disclosure of any contact of an adjacent vertebra by a band 14. For that matter, bands 14 are not restrained against movement relative to an insert as recited in claim 19; instead, it is the bands 14 that function (as described in that patent) to “restrain.” Reconsideration and withdrawal of the rejection of claim 19 over the Pisharodi ‘926 patent is respectfully requested in light of these several differences between the method described in that patent and the method recited in claim 19.

Claims 24, 25, and 35 are all dependent on claim 19 and all recite additional detail that further illustrates the shortcomings of this §102 rejection. Claim 24, for instance, recites that the insert is comprised of relatively incompressible material. If the bands 14 described in Pisharodi ‘926 are to function for their stated purpose of maintaining the prosthesis 2 described in that reference “in a shape and size suitable for insertion [of the prosthesis] through a one square centimeter opening into the disk space” (quoting from col. 3, lines 42-44 of the ‘926 patent), they must themselves almost necessarily be comprised of a stretchy, elastic material. Such materials are generally of a character that is exactly the opposite of a material that is “relatively incompressible” as recited in claim 24. Indeed, the bands are described in the ‘926 patent as being preferably comprised Silastic (see col. 3, line 41), a material that is undoubtedly familiar and that is characteristically compressible such that it is improper to reject claim 24 over the ‘926 patent. Claim 25 recites that the insert is restrained against movement relative to the implant until after the implant is inserted into the space from which a portion of the disk has been removed, illustrating the distinction to which Applicant has previously directed attention between the prosthesis 2 disclosed in Pisharodi ‘926 and the present invention, namely the prosthesis 2 described in Pisharodi ‘926 is intended as a replacement for an intervertebral disk. Claim 25 recites that the implant of the present invention is inserted into a space from which a portion of the intervertebral disk has been removed and the Pisharodi ‘926 patent discloses a device that replaces the entire disk and is therefore very different than the implant of the present invention. With regard to claim 35, of course there is no risk of extrusion of the prosthesis 2 out of the disk space as disclosed at col. 3, lines 55-57 of Pisharodi ‘926 and to which the Official Action of March 19, 2009 directs attention because the prosthesis 2 described in the Pisharodi ‘926 patent is a prosthesis that replaces a damaged or diseased intervertebral disk and when it is placed in the disk space, it occupies the entire disk space. That structure and function is very different than the step of resisting movement of an implant such as the implant of the present

invention out of a disk space as recited in method claim 35 (which is one reason that claim 19, on which claim 35 depends, recites that a portion of the disk is removed). Reconsideration and withdrawal of the §102 rejection of claims 24, 25, and 35 is respectfully requested.

Turning now to the §102 rejection over the Perren patent, at the top of page 4, the Action alleges that either of the upper or lower plates 1, 2 of Perren is movably mounted relative to the implant and that the connecting means 4 described in that patent “allows relative movement” between the two plates. Applicant agrees that the connecting means 4 of the device disclosed in Perren allows relative movement of the plates (both plates are actually designated in Perren by reference numeral 1 rather than reference numerals 1 and 2), but does not agree that the plates move relative to the implant. Nor does Applicant agree that the connecting means 4 “biases” as alleged in the third and fourth lines of page 4 of the Action. There is no description in Perren of the springiness or compressibility of the SMA connecting means 4; Perren describes only a first relative position of plates 1 that is of smaller volume for introduction into the disk space and a second relative position of plates 1 of a “more voluminous configuration as shown in Fig. 3 which is designed to provide optimal spacing function for the two adjacent vertebrae” (quoting from col. 3, lines 28-30 of Perren). Clearly Perren discloses only that the two plates are either held a first, shorter distance apart (to facilitate introduction into the disk space) or a second, “more voluminous” distance apart (to provide optimal spacing of the adjacent vertebra). There is no disclosure of any spacing of plates 1 at any distance between the first and second distance, nor is there any disclosure of any spring function of the connecting means 4. If any such function of SMA materials is known to the Examiner, it is respectfully requested that evidence of that function be made of record by affidavit in accordance with the requirements of MPEP §2144.03, 4th ¶.

A further distinction between the implant utilized in the method of the claimed invention and the prosthetic disk disclosed in Perren is highlighted by the recitation in claim 19 that the implant of the present invention is elongate. The device shown in Figs. 1 – 3 and 5 of Perren is anything but elongate (and the device shown in Fig. 4, which might be argued to be elongate, will not function for the intended purpose as a disk prosthesis until it assumes the “non-elongate” shape shown in Fig. 5). Because the Perren device is not elongate and therefore does not have a longitudinal axis about which rotation can be resisted as recited in the last step of the method claimed in claim 19 (and as set out above, the phrase “longitudinal axis” has been amended to “insertion axis” as suggested in the Official Action of April 19, 2009, and Perren does not disclose a device with an insertion axis either), Perren cannot anticipate claim 19. In fact, as pointed out at page 8 of Applicant’s Response to Official Action of November 19, 2008 (*sic*,

2007), there is no disclosure of resisting rotation anywhere in the Perren patent. Reconsideration and withdrawal of the §102 rejection of claim 19 over the Perren patent is respectfully requested in light of these several differences between the device disclosed in that patent, and the manner in which it is used, and the method of claim 19.

Claims 24-27, also rejected under §102 over Perren, are allowable because they depend upon a main claim that is allowable over Perren. However, each of claims 24-27 recite method steps that are not disclosed in Perren and so each of those claims is also allowable on its own merits. Contrary to the allegation in the one-sentence paragraph on page 4 of the Action, there is no disclosure in Perren of a spring for biasing as called out in claim 24. As set out above, there is no suggestion that the connecting means 4 described in Perren functions as a spring and if such function is known to the Examiner, Applicant repeats the request that such evidence be made of record in accordance with the requirements of MPEP §2144.03. There is no disclosure in Perren of restraining the two plates 1 against relative movement as recited in claim 25 (instead, the connecting means 4 simply causes the two plates to be positioned at a first, closely spaced position or a second, “more voluminous” position). There is no disclosure in Perren of anything that is springy and compressible as recited in claim 26. The remarks set out above as to the differences between the implant of the present invention, which is inserted into the space from which (as recited in claim 27) a portion of the disk has been removed, and the disk prosthesis of Perren, which is intended to replace a disk, are re-asserted here in traversing the §102 rejection of claim 27 over Perren. Reconsideration and withdrawal of the §102 rejection of claims 19 and 24-27 over Perren is respectfully requested in light of these many differences between Perren and the method of the claimed invention.

Turning now to the §103 rejection of claims 2 and 28-34 over Pisharodi ‘926 in view of Steffee or Pisharodi ‘762, this rejection is respectfully traversed for failure to make out a proper *prima facie* showing of the obviousness of the differences between the claimed invention and the combination of the cited references. As set out in the second paragraph of MPEP §706.02, “[t]o establish a *prima facie* case of obviousness, three criteria must be met”: (1) the rejection must indicate some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings, (2) there must be some expectation of success, and (3) the prior art references must teach or suggest all the claim limitations. Because the Action fails to establish these required criteria for a proper *prima facie* showing of the obviousness of the differences between the invention claimed in claim 2 and the cited prior art references, Applicant respectfully traverses the §103 rejection of claim 2. Specifically, none of the cited references,

alone or in combination, discloses an implant with an insert mounted to it on a spring and movable relative to the insert as recited in the first paragraph of claim 2. Nor do any of the references disclose an insert that is restrained against movement relative to an implant that is inserted into a disk space, or an insert that is released from an implant and biased toward the adjacent vertebra, all as recited in the third paragraph of claim 2. As summarized above in connection with the §102 rejection of claim 19, and contrary to the allegation in the middle of page 4 of the Action, the bands 14 described in the Pisharodi '926 patent are not biased toward an adjacent vertebra. Nor are they mounted to an implant on a spring. Further, Application traverses the allegation (two-thirds of the way down page 8 of the Action) that the device disclosed in Pisharodi '926 is rolled into a rectangular shape. It is therefore irrelevant that the Pisharodi '762 and/or Steffee patents might disclose re-orienting an implant after insertion. Applicant also traverses the allegation that the Pisharodi '762 and Steffee patents are "similar" to the implant of the subject invention.

In addition to the failure of the cited references to disclose at least two of the three steps recited in claim 2, the Action fails to establish a proper *prima facie* §103 rejection of claim 2 because no suggestion or motivation to combine the cited references is set out in the Action. At the top of page 5 of the Action, it is alleged that a smaller incision produces less trauma to the patient, but looking back to the bottom of page 4, it is clear that this allegation is being suggested only as a motivation for re-orienting an implant in a disk space, not as a suggestion or motivation to combine certain specific elements or steps described in the three references to make the claimed combination. There is no allegation, for instance, that because of X, one skilled in the art would be motivated to combine the Q of reference A with the R of reference B and, because of Y, one would be motivated to combine the S of reference C with the QR combination. Applicant is of course aware that the suggestion or motivation to combine need not be explicit, but as set out in MPEP §2142,

"[w]hen the motivation to combine the teachings of the references is not immediately apparent, it is the duty of the examiner to explain why the combination of the teachings is proper [citation omitted]" and, as set out at MPEP §2143.01, ¶4, "[a] statement that modifications of the prior art to meet the claimed invention would have been 'well within the ordinary skill of the art at the time the claimed invention was made' because the references relied upon teach that all aspects of the claimed invention were individually known in the art **is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references** [citation omitted, underlining in original, bold emphasis added]."

As a further indication of the insufficiency of the §103 rejection of claim 2, it is also noted that a *prima facie* showing of the obviousness of the differences between a claimed invention and the

references relied upon must also include a showing that there is a reasonable expectation of success in combining the reference teachings. MPEP §§2142, 2143.02. It does not appear that the Action even made an attempt to establish this requisite showing of success. In short, because the Action fails to establish any of the three elements required for a proper *prima facie* showing of obviousness (disclosure of all the claimed elements, a reasonable expectation of success, and a teaching to combine), it is respectfully submitted that the §103 rejection of claim 2 is improper, and for that reason, reconsideration and withdrawal of the rejection is respectfully requested.

Claims 28-34, being dependent on an allowable main claim, are likewise allowable, but each of those dependent claims adds subject matter that is likewise not disclosed in the patents cited in making this §103 rejection such that the Action also fails to establish a proper *prima facie* rejection of those claims. Because the cited references do not disclose the step of restraining an insert against movement for insertion of an implant into the disk space, it is clear that the references do not disclose the step recited in claim 28 that the insert is restrained until after the implant has been inserted. Even if it is possible to somehow get past the complete lack of any disclosure of an insert mounted to an implant that is movable relative to the implant on a spring in the Pisharodi '762 and Steffee patents, there is no disclosure in those patents that an insert, or any other portion of an implant, should be comprised of a compressible material. Nor is there even any teaching or suggestion that the implants disclosed in those patents should be comprised of more than a single material. The language near the top of page 5 of the Action addressing claim 30 is so unclear as to be incapable of being understood. There is no description in any of the cited patents of anything that is maintained in alignment in accordance with claim 31, and indeed, the Action sets out no such allegation. Nor does the Action suggest that rotation of the implant is resisted as recited in claim 32, which was also rejected under §103 over the combination of the Pisharodi '926, Pisharodi '762, and Steffee patents. Referring to claim 33, page 5 of the Action alleges that the flanges of the spikes 8 limit movement away from the implant, but there is no allegation that the spikes constitute an insert as claimed or that movement of such an insert is limited as recited in the claim. To the contrary, the Action alleges (on page 3) that "the insert as claimed is band (14) of Pisharodi ['926]," not the spikes 8. Because these several elements recited in claims 28-34 are not disclosed in the cited patents, it is respectfully urged that the §103 rejection of claims 28-34 be reconsidered and withdrawn.

It is alleged at the middle of page 5 of the Action that it would have been obvious to combine the teaching of a collagen gel in the Muhamna patent with the "Pisharodi implant" such that claims 20-21 are obvious and therefore unpatentable under §103. This rejection is also respectfully traversed in part because it is not apparent which "Pisharodi implant" is being

referenced in making this rejection. The rejection is also traversed because, contrary to the allegation that it would have been obvious to combine them, one skilled in the art would not be motivated to combine the cited references. Throughout the prosecution of the captioned application, Applicant has drawn attention to the differences between prosthetic disks (meant to replace the patient's natural intervertebral disk) and implants that are intended for use after a portion of the disk has been removed for use in procedures as fusion of two adjacent vertebrae, and this rejection of claims 20-21 highlights another example of why this distinction is important. Specifically, there is no reason to pack the space around a disk prosthesis with bone chips or the gels recited in claims 20-21 for the purpose of preventing rotation of the prosthesis; preventing rotation is only relevant for an implant such as is described in the captioned application or in the Pisharodi '762 patent (indeed, bone chips are used to promote fusion and resist rotation, and because a prosthesis is intended to mimic the function of a normal intervertebral disk, packing bone chips around a disk prosthesis would actually interfere with the function of the prosthesis). Because the Pisharodi '926 and Muhanna patents disclose devices that are intended to replace an intervertebral disk, one skilled in the art would not insert a gel round those devices and one skilled in the art would not, therefore, be motivated to combine the disclosures of these three patents. Without regard to the issue of whether the cited references disclose all the elements recited in claims 20-21 (and as set out above, they do not), because the rejection of claims 20-21 fails to establish a proper motivation to combine the cited references, it is respectfully submitted that a *prima facie* rejection of those claims has not been established.

Finally with regard to the §103 rejection of claims 22-23, Applicant re-asserts the remarks set out above as to the lack of any motivation to combine the cited Pisharodi '926, Pisharodi '762, and Muhanna patents, as well as the cited Haldimann patent, and respectfully suggests that the Action fails to establish a proper *prima facie* §103 rejection of claims 22-23 for the same reason as for claims 20-21.

Before concluding this Response, Applicant needs to address the allegation on page 6 of the Action (under the heading "Response to Arguments") that "[t]he mere functional difference does not clearly suggest a different structure." First, as set out above, Applicant **has** defined differences in structure in his claims. Second, Applicant again calls attention to the framing of the claims of the captioned application as **method**, not apparatus, claims and function is indeed capable of distinguishing over prior art when recited as steps of a method. There are no allegations in the Action that the prior art devices anticipate Applicant's claims by carrying out the claimed method during normal operation of the prior art devices (the inherency type of rejection contemplated by MPEP §2112.02), nor are Applicant's claims worded as apparatus

claims that rely on functional language in an attempt to define over a prior art device as contemplated by MPEP §2114. To the contrary, it is respectfully submitted that, to the extent that Applicant's claims do recite structure, the structural recitations are exactly the type of claim language contemplated by MPEP §2117 that "manipulatively distinguishes" the claims from the prior art and are therefore entitled to "patentable weight." As set out at length above, the cited references, alone or in combination, fail to disclose several of the structural features recited in Applicant's claims, and Applicant's reliance on such recitations to distinguish over the prior art do not "amount to mere claiming of a use of a particular structure" (quoting Ex parte Pfeiffer, 135 U.S.P.Q. 31, 33 (Bd. Pat. App. Intfs. 1961), cited with approval in MPEP §2117).

Entry of the above amendments, consideration of the remarks set out herein, allowance of the claims, and passage of the application to issuance are all respectfully requested. In the event there are questions and/or issues yet to be answered in this application, it is respectfully requested that Applicant's Attorney be contacted at the address and phone number set out below.

Respectfully submitted,



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